UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHING M. CHUNG,
LILY CHAN,
KELI OU,
SHAO-EN ONG,
TECK K. SEOW,
CYNTHIA R.M.Y. LIANG
MENG L. CHOONG, and
LI K. TAN

Appeal No. 2004-2201
Application No. 09/788,476

ON BRIEF[1]

WILLIAM F. SMITH, MILLS, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claim 1. Claims 15-17 are stated by appellants to have been indicated allowable by the examiner. Appeal Brief received December 10, 2003, page 2.

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[1] We note that a request for oral hearing was made on pages 5-6 of the Reply Brief. Requesting oral hearing in a Reply Brief did not comply with the then existing provisions of 37 CFR § 1.194(b)("If appellant desires an oral hearing, appellant must file, in a separate paper, a written request for such hearing . . .."). In view of our disposition of the appeal, appellants' request for oral hearing is moot.

1. An isolated nucleic acid comprising the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO:3 or a nucleotide sequence, having at least about 60% similarity to the full length of SEQ ID NO:1 or SEQ ID NO:3, that hybridizes to SEQ ID NO:1 or SEQ ID NO:3 under conditions of 0.1 x SSC buffer, 0.1% w/v SDS, at a temperature of at least 65°C, wherein an mRNA corresponding to said nucleic acid is differentially or preferentially expressed in human hepatocellular carcinoma tissue or tissue from pancreatic adenocarcinoma relative to other tissue in said subject and/or in subjects not diagnosed with this condition.

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph (written description and enablement). The examiner does not rely upon any evidence in support of these rejections. We reverse.

Background

Appellants discuss the present invention at page 21 of the specification as follows:

> The present invention is described hereinafter with reference to the detection of one particular gene designated hcc-1 from the human hepatocellular carcinoma cell line, HCC-M. The nucleotide sequence of hcc-1 is provided in SEQ ID NO:1. The corresponding expression product is a protein designated HCC-1 and this comprises an amino acid as set forth in SEQ ID NO:2. A PCR extended form for use in a vector is shown in SEQ ID NO:3.

As seen, claim 1 is directed to an isolated nucleic acid comprising the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO:3. In addition, claim 1 comprises a nucleotide sequence having at least about 60% similarity to the full length of SEQ ID NO:1 or SEQ ID NO:3 that hybridizes to SEQ ID NO:1 or SEQ ID NO:3 under specified conditions. In addition, the third nucleotide sequence encompassed by claim 1 is required to have an mRNA that corresponds thereto that is differentially or preferentially expressed in

human hepatocellular carcinoma tissue or tissue from pancreatic adenocarcinoma relative to other tissue in the subject and/or in subjects not diagnosed with this condition.

Discussion

1. Written Description.

The Federal Circuit discussed the application of the written description requirement to inventions in the field of biotechnology in University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), stating that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. at 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. at 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

Both appellants and the examiner believe that the written description issue raised in this rejection is similar to the issue raised in Example 9 of the training materials issued in conjunction with the USPTO written description guidelines. See, "Synopsis of Application of Written Description Guidelines," at 35, available at http://www.uspto.gov/web/menu/written.pdf. The hypothetical claim which is the subject of Example 9 of the Guidelines reads as:

> an isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO:1, wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.

We first note that the hybridization conditions set forth in claim 1 on appeal are stated to be "high stringency." Specification, page 25, lines 3-4. The examiner's reasoning as to why the present fact situation is not analogous to that set forth in Example 9 of the Guidelines is as follows:

> In the hypothetical claim 1 of Example 9 in the Guidelines, the structure of the claimed genus encodes a protein with the recited function. In other words, the recited function is dictated by the chemical structure of the claimed genus.

> However, unlike the situation in Example 9 of the Guidelines, the instantly recited function is not associated with the structural feature of claimed genera, but associated with human disease status. In the instant claim 1, the recited function is not dictated by chemical structure of the claimed genus but dictated by other events i.e. that pancreatic adenocarcinoma or HCC is developed in a host. In other words, the expression is not function associated with the structure but a reaction of a human body to certain stimuli, in the instant case the development of HCC or pancreatic adenocarcinoma.
>
> In summary, the functional characteristic recited is uncoupled with the structure of the claimed genus. There is no correlation between the chemical structure of the claimed genus and the recited function. Therefore the recited functional language describing the claimed genera does not adequately describe the common feature of claimed generic nucleic acid molecule.

Examiner's Answer, pages 8 and 9.

The analysis of the reasoning set forth in Example 9 of the Guidelines as to why hypothetical claim 1 of that example complies with the written description requirement is as follows:

> Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill in the art are adequate to determine that applicant was in possession of the claimed invention.

Guidelines at 36-37.

We disagree with the examiner's analysis that claim 1 on appeal does not comply with the written description requirement because the expression of the claimed nucleic acid is "not function associated with the structure but a reaction of the human

body to certain stimuli, in the instant case the development of HCC or pancreatic adenocarcinoma." Example 9 of the Guidelines does not place any restriction as to how the coding function of the DNA may be claimed. A determination whether a given nucleic acid is within the scope of the hypothetical claim of Example 9 of the Guidelines would require expressing the nucleic acid and testing the protein to determine whether it binds to a dopamine receptor and stimulates adenylate cyclase activity. A determination whether a given nucleic acid is within the scope of claim 1 would also require testing, albeit different testing. According to the terms of claim 1, an mRNA corresponding to the nucleic acid must be differentially or preferentially expressed in human hepatocellular carcinoma tissue or tissue from pancreatic adenocarcinoma relative to other tissue in said subject and/or in subjects not diagnosed with this condition. The examiner states that the functional characteristic recited in claim 1 is "uncoupled with the structure of the claim genus," Examiner's Answer, page 9, but does not explain why that is significant in determining whether claim 1 complies with the written description analysis. The training materials are not the end-all of a written description analysis. The fact that a given claim under review does not fit squarely within one of the examples does not mean that that claim does not comply with the written description requirement. Rather than merely pointing out that claim 1 differs from the hypothetical claim in Example 9 of the Guidelines, an analysis is needed from the examiner explaining why the function set forth in claim 1 is not an adequate identifier of the claimed genus of nucleic acids. Instead, all we have is the examiner's

conclusion that claim 1 on appeal is different from the hypothetical claim of Example 9 of the Guidelines and therefore claim 1 on appeal does not comply with the written description requirement. This is insufficient.

The examiner's rejection under 35 U.S.C. § 112, first paragraph (written description), is reversed.

2. Enablement.

In stating the rejection on pages 5-6 of the Examiner's Answer, the examiner has focused on the purported need to screen a "large quantity of clinical samples" in order to enable claim 1 throughout its scope. In reviewing the examiner's response to arguments in regard to this rejection on pages 10-13 of the Examiner's Answer we find the examiner again focuses on the need to screen "a large quantity of clinical samples." Id., page 10. As stated at page 11 of the Examiner's Answer, "in order to make the full scope of the invention, one skilled in the art has to screen a large quantity of clinical samples from liver or pancreatic tissue of patients having HCC or pancreatic adenocarcinoma, followed by sequence [sic] the nucleic acid composition."

As set forth in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996):

> In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d. 1200, 1212-14, 18 USPQ2d 1016, 1026-

> 28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation 'must not be unduly extensive.' Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:
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> > The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

What is missing is an analysis from the examiner as to why the amount of work required to practice the invention of claim 1 throughout its scope would be considered undue instead of routine. It is insufficient for an examiner to merely point out that it is necessary to "screen a large quantity of clinical samples." Examiner's Answer, page 11.

Accordingly, the examiner's rejection under 35 U.S.C. § 112, first paragraph (enablement) is reversed.

The decision of the examiner is reversed.

REVERSED

William F. Smith Administrative Patent Judge	)
Demetra J. Mills Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
Eric Grimes Administrative Patent Judge	)

Birch, Stewart, Kolasch, & Birch
P.O. Box 747
Falls Church, VA 22040-0747

dems